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EXAMINER	
REICHLE, KARIN M	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,313	OSBORNE ET AL.	
	Examiner	Art Unit	
	Karin M. Reichle	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6-07 and 12-07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,9,11,12,16,18-20,22,25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9,11,12,16,18-20,22,25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The following action on the merits is based on the 12-10-07 response and the remarks of the 6-22-07 response.

Specification

Description

2. The disclosure is objected to because of the following informalities: 1) In paragraph 36 as originally filed a housing (or cannula housing as now amended) 10 having a passage 11 is described as including a member (or housing member as now amended) 12 having an abutting surface and a cap 17 having a recess 18 threaded onto the member 12 with a valve body 1 received in the recess 18 and abutting the member 12, i.e. mounted to such member but not in the passage. The claims now, and still, require a housing member having a passage and a cap having a recess with a valve body to be received in the recess and mounted to the housing member in the passage. At the very least, see also the discussion in paragraph 3 infra, it is still unclear whether the housing member as claimed is the housing/cannula housing or housing member/member as described. If the former, consistent terminology should be used throughout the description and the claims, see MPEP 608.01(o), i.e. the housing member as claimed should be called the "housing" or "cannula housing", and a consistent description of the valve body with respect to such housing should be set forth throughout the application, i.e. the housing includes, as originally described and shown, the valve body 1 mounted to or abutting one end of a passage 11

of the housing 10 so as to span such end while received by the recess 18 of the cap 17 as compared to a valve body to be received in the recess and mounted to the housing member in the passage as now claimed. If the latter, a consistent description of the valve body with respect to the housing member should be set forth throughout the application, i.e. as originally described and shown the valve body 1 is mounted to or abuts the housing member 12 so as to span one end of the passage 11 of the housing 10 while received by the recess 18 of the cap 17 threaded onto the member as compared to a valve body to be received in the recess and mounted to the housing member in the passage as now claimed. See the Claim Language Interpretation section infra. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-3, 7, 9, 11-12, 16, 18-20, 22, 25 and 27 are rejected under 35U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 now requires a medical instrument comprising: a housing member having a passage through which a catheter including an outer profile is received; a cap having a recess formed therein and in fluid communication with the passage, the recess being defined by recess dimensions; and a valve body to be received in the recess and mounted to the housing member in the passage, the valve body having first and second faces and a peripheral edge separating the faces, the peripheral edge being non-circular when the valve body is unstressed, the valve body further having a first slit formed on one of the

faces and a second slit formed on the other face, each slit formed through a portion of the valve body and intersecting with the other slit within the valve body, the valve body conforming to the outer profile of the catheter when the catheter is disposed through the first and second slits to maintain a fluid tight seal between the valve body and the catheter, the valve body having a height dimension across **the center** of the valve body and a width dimension across **the center** of the valve body, the width dimension being less than the height dimension when the valve body is unstressed, the height and width dimensions being unequal to the recess dimensions, **defining a plane parallel to the first and second faces and perpendicular to the slits**, the valve body configured to be **compressed only along the height dimension** when the valve body is received by the recess, producing a closing force on the slit after removal of a catheter to prevent leakage, defining a generally circular shape. While original claims 1, 5-6 and 8, for example, set forth a medical instrument comprising: a housing having a passage through which a catheter is received and a recess with a dimension thereacross, i.e. but no cap with a recess defined by dimensions, a valve body mounted in the passage of the housing, the valve body having a two opposing planar faces and a peripheral edge separating the faces which edge is non-circular when the valve body is unstressed before being received in the recess of the housing, the valve body further having a first slit that opens in one of the planar faces and a second slit that opens in the other planar face, each slit extending partly through the valve body and intersecting with the other slit within the valve body, the valve body conforming to the outer wall of the catheter when the catheter penetrates through the intersection of the first and second slits to maintain a fluid tight seal between the valve body and the catheter, the valve body having a first planar dimension across the first or second planar face through the center of the valve body and a

second planar dimension across the first or second planar face through the center of the valve that is less than the first planar dimension when the valve body is unstressed before being mounted in the passage of the housing, the first planar dimension being greater than the dimension across the recess of the housing, the valve body being compressed along the first planar dimension when the valve body is received within the recess of the housing, and the original application, e.g., Figures 1-2, 9-10 and paragraph 42, for example, set forth a medical instrument comprising: a housing member having a passage through which a catheter including an outer profile is received, a cap having a circular recess formed therein which is in fluid communication with the passage, the recess being defined by recess dimensions, and a valve body having an oval shape before being received in the recess when the valve body is unstressed and received in the recess and mounted to the housing **member** spanning the passage, the valve body having first and second opposing planar faces or opposing planar faces with specifically located rings and a peripheral edge separating the faces, the peripheral edge being non-circular when the valve body is unstressed before being received in the recess, i.e. mounted in the passage of the housing, spanning the passage of the housing **member**, the valve body further having a first slit formed on one of such disclosed faces and a second slit or opening formed on such disclosed other face, each slit formed through a portion of the valve body and intersecting with the other slit within the valve body, the valve body conforming to the outer profile of the catheter when the catheter is disposed through the first and second slits to maintain a fluid tight seal between the valve body and the catheter, the valve body having a height dimension across the center of the valve body and a width dimension across the center of the valve body, the width dimension being less than the height dimension when the valve body is unstressed before being

received in the recess, the height dimension being greater than a height dimension across the center of the circular recess and the width dimension being less than a width dimension of the circular recess, defining a plane parallel to the first and second faces and perpendicular to the slits, the valve body configured to be compressed only along the peripheral edge parallel to the height dimension when the valve body is received by the recess, producing a closing force on one of the slits after removal of a catheter to prevent leakage and so as to define a generally circular shape, this is not what appears to be claimed now, i.e. what is claimed now is both narrower with regard to some aspects and broader with regard to other aspects than the invention as originally described and claimed. Attention is also reinvited to the discussion in paragraph 2 supra. The discussion of claim 1 applies to claims 19 and 27 which have been similarly amended, or added and similarly written, respectively, as compared to the original claims and application. While Applicant has provided reference to certain portions of the original application in the remarks of 12-07 and 6-07, such portions do not support the entire scope of the invention of each claim as now presented in a single embodiment. For example, while Figures 2, 10 and 12 and paragraph 41 disclose the valve body being compressed only along the peripheral edge parallel to the height dimension so as to produce a closing force on one slit, i.e. along all the planes perpendicular to the edge and parallel to the height dimension, to define a valve body of circular shape when received in the recess of the cap and mounted across the passage, this is not what is claimed, i.e. it is claimed the height dimension defines a plane with the width dimension across the center of the valve body and the valve body is only compressed along such dimension/plane when received by the recess to define a circular shape in claim 1 (It is noted that the circular shape would appear to be only along such plane) and it is claimed it produces on

force on the slits in claim 27 but the force is only produced on the one slit. Furthermore, it is noted that as set forth in paragraph 36 the valve body appears to be sandwiched/compressed between the cap and housing member when received and mounted across the passage. Therefore, if Applicant maintains the claim language, the portion of the originally filed application which provides support for the scope of the combination of each claim in a single embodiment should be set forth. See the Claim Language Interpretation section supra.

Claim Language Interpretation

4. Due to the lack of clarity, see discussion in paragraph 2 supra, the claims will be interpreted to require at the very least a valve body which has the capability of being received in the recess and is mounted to the housing member across the passage. It is noted that the cap as claimed is not required to be a distinct element, i.e. can be monolithically formed with the member. With regard to all the claims, see the discussion of paragraph 3 and MPEP 2163.06, I. Also, the "recess dimensions" which define the recess, e.g. line 5 of claim 1, will be interpreted as all such dimensions of the recess and thereby, the claim limitation regarding such dimensions with respect to the valve body dimensions, i.e. "dimensions unequal to the recess dimensions", will be interpreted to require dimensions unequal to the dimensions of the recess before such is received therein, i.e. the claimed dimensions of the valve body are either larger or smaller than the dimensions of the recess before receipt therein.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-3, 7, 9, 11-12, 16, 18 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al '665 in view of Dudar et al '394, Picha et al '654, Muto '548, Spademan '127 and Shimonaka et al '679.

Claim 1 : See Figures, especially 24A-24B, col. 1, lines 6-10, col. 2, lines 20-28, col. 4, line 64-col. 6, line 9, col. 14, lines 29-42, col. 15, line 63-col. 16, line 2 and col. 18, lines 12-46 of '665, e.g. '665 teaches a medical instrument 10 comprising a housing member 11 having a passage 14 through which a catheter including an outer profile is received, a cap 12 having a recess formed therein and in fluid communication with the passage and defined by recess dimensions and a valve body, 16, 80, 120, 130, or 140, received in the recess, i.e. and thereby having the capability of being received therein, see the Claim Language Interpretation section supra, and is mounted to the housing member across the passage, see Claim Language Interpretation section supra, the valve body having two faces and a peripheral edge separating the faces, see, e.g., Figures 24A-B, the peripheral edge being non-circular when the valve body is unstressed, the valve body having a first slit, 131 or 132, formed on one of the faces and a second slit, 132 or 131, formed on the other face and each slit extends partly through the valve body and intersects the other slit therewithin. As disclosed at the cited portions, the valve body conforms to the outer profile of the catheter when the latter is disposed through the intersection of the slits to maintain a fluid tight seal therebetween. The valve body, e.g. 130, has first and second dimensions through the center of the valve body, e.g., the longitudinal/"height" dimension and

transverse/"width" dimension, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage. The height dimension and the width dimension define a plane parallel to the first and second faces and perpendicular to the slits. Claim 1 now requires 1) the height and width dimensions being unequal to the recess dimensions, see the Claim Language Interpretation section supra, e.g. the longitudinal/"height" dimension and the transverse/"width" dimension of the valve body being greater than the similar dimensions of the recess, and the valve body configured to be compressed only along the height dimension when the valve body is received by the recess (It is noted that such does not require such compression when received and mounted as set forth on line 6) and 2) defining a generally circular shape. With regard to 1), it is noted that while the Figures show the valve disc having the same diameter as the recess and the valve body 130 having at least a length greater than the diameter of the circular valve body, '665 does not explicitly describe the valve body 130 having the dimensions as claimed. However, also note in addition to the portions of '665 already cited supra, e.g. the abstract and col. 3, lines 60-62, i.e. '665 desires its valve body, e.g. body 130, received in a tubular/circular housing, 11, 12, be capable of receiving a rodlike member such as a catheter, guide wire, syringe tip or needle in a liquid tight manner and also be liquid tight after removal thereof. Furthermore, it is well known in the medical art to make the dimensions of a valve body, whether pre-slit, partially pre-slit or slit upon first use, received in a tubular/circular recess unequal to the recess dimensions, i.e. make the "height" and/or "width" dimensions larger than similar dimensions of the recess, e.g. make the height dimension larger than the recess so that compression is along only a plane across the center of the valve body, so as to receive, i.e. good insertability, a rodlike member, i.e. a catheter, syringe tip, needle, in a liquid tight manner, and

also be liquid tight after removal thereof. See, e.g., Dudar et al '394 at, e.g., Figures 15 and 23, col. 2, lines 36- 40, col. 3, lines 16-20 and 50-52, col. 7, lines 42-47 and 52-54, col. 8, lines 38-53 and col. 10, lines 47-55 (note Figure 13 of '665), Picha et al '654 at, e.g., the Figures, the abstract, col. 3, lines 9-20 and 27-35 and col. 4, lines 1-9, Muto '548 at, e.g., the Figures, the abstract and col. 4, lines 5-7, Spademan '127 at, e.g., the abstract, Figures 4A-7D, col. 3, line 3-col: 4, line 2 (Note col. 3, lines 37-39 with regard to the added claim language) and col. 4, lines 39-51; and Shimonaka et al '679 at, e.g. the Figures and the abstract and col. 2, lines 5-17 and 23-41. To make the valve body of '665 with dimensions unequal to those of the recess which receives such valve body as claimed, i.e. the height dimension only, would be obvious to one of ordinary skill in the medical arts in view of the recognition that such sizing of a valve body relative to a recess is well known not only to promote liquid tightness of a valve body while receiving a rodlike member and also after withdrawal thereof but also good insertability such as, for example, taught by Dudar et al '394, Picha et al '654, Muto '548, Spademan '127 and Shimonaka et al '679 and the desire by '655 for the valve body thereof to seal in a liquid tight manner both while receiving/inserting a rodlike member and after withdrawal thereof. In so doing the prior art would also necessarily and inevitably compress the valve body only along the enlarged dimension, i.e. the height dimension thereof, when the body is received in the recess. With regard to 2) i.e. the valve body defining a generally circular shape, see Figures 3-4 and 24A-B as well as, e.g., col. 5, lines 15-18. Therefore, while the '665 does not explicitly teach the valve body having a generally circular shape when mounted in the passage of the housing, there is sufficient factual evidence for one to conclude that the flexible elastomeric valve body of Figures 24A-B would necessarily and inevitably assume or have a generally circular shape when

mounted in the circular passage of the circular housing. Note also, e.g., Figures of Spademan '127 and Shimonaka '679.

Claim 27: See discussion of claim 1 supra. The prior art additionally necessarily and inevitably produces a closing force on the slits after removal of the catheter to prevent leakage.

Claims 2-3 and 11-12: See Figures cited supra.

Claims 7 and 16: See Figures 3-4.

Claims 9 and 18: Applicants claim the peripheral edge has an oval shape when the valve body is unstressed before being received in the recess, i.e. a shape which is longer along one axis than the other. While the prior art does not teach an oval shape, it does teach a shape which is longer along one axis than the other in combination with a circular recess, see Figures 3-4 and 24A-B of '665. Furthermore, see paragraphs 42, 66 and 70 and Figures of the instant application, i.e. no disclosure of the criticality of the oval shape over any other shape which has one axis longer than the other axis, e.g. a rectangle or the shape shown in Figures 11-12, i.e. just one of numerous shapes for the purpose of providing a shape having different dimensioned axes. Therefore, it would be an obvious matter of design choice to employ an oval rather than a rectangle on the '655 device since such modification would have involved a mere change in the shape of the component. A change in shape is generally recognized as being within the level of ordinary skill in the art, i.e. an oval is just one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing a shape having different dimensioned axes, In re Dailey 149 USPQ 47. Note also the Figures of Spademan ' 127 and Shimonaka '679.

7. Claims 19, 20, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behnke et al '034 in view of Thomas et al '463.

It is noted that the effective filing date of claims 19, 20, 22 and 25 is 10-24-95.

Claim 19: See Figures 3 and 7, and col. 1, lines 5-7, col. 3, lines 19-33 and col. 6, lines 11-48 of '034, e.g. '034 teaches a medical instrument 10A comprising a housing member, e.g. the lower portion of 16A, having a passage through which a cannula having an outer profile, i.e. a catheter, is received, a cap, e.g. the upper portion of 10A, i.e. adjacent 18A, having a recess formed therein, e.g. at least the portion of 10A above the bottom of 102, and in fluid communication with the passage and defined by recess dimensions and a valve body, 22A, received in, i.e. and thereby having the capability of being received therein, see the Claim Language Interpretation section supra, and is mounted to the housing member across the passage, see Claim Language Interpretation section supra, the valve having two faces and a peripheral edge separating the faces, see, e.g., Figure 7, the valve body having a slit, 30A, that defines a slit plane extending from a first face, an opening 28A extending from the second face and partly through the valve body to intersect with the slit therewithin which includes an internal ring adjacent 32A as claimed. As disclosed at the cited portions, the valve body conforms to the outer profile of the cannula, i.e. the catheter, when the latter is disposed through the slit plane and ring to maintain a fluid tight seal therebetween. The valve body has first and second dimensions through the center of the valve body, i.e. the valve body has a "height" dimension, e.g. a diameter thereof, e.g., through the portion 38, and a "width" dimension, e.g., another diameter thereof, e.g. through the portion 38, the height dimension and the width dimension defining a plane parallel to the first and second faces and perpendicular to the slits, the height

and width dimensions being unequal to the recess dimensions, the valve body configured to be compressed along the height dimension when the valve body is received by the recess, producing a closing force on the slit after removal of a catheter to prevent leakage, and defining a generally circular shape, i.e. see the Claim Language Interpretation section supra, and, e.g., Figures 3 and 7 and col. 3, lines 19 et seq of '034. Claim 19 now claims the peripheral edge being non-circular when the valve body is unstressed and the width dimension being less than the second height dimension when the valve body is unstressed, whereas the valve body of '034 teaches the edge being circular, i.e. the height and width dimensions being equal to each other, when such is unstressed. However, again '034 does teach a valve body sized with respect to the recess such that the valve body is compressed about the periphery adjacent the slit to ensure closing of the slit, see cited portions of '034. Furthermore, see '463 at col. 4, line 31-col. 5, line 12, i.e. interchangeability of a valve body sized with respect to a recess such that the valve body is compressed about the periphery to ensure closing of the slit with a valve body having an oval peripheral edge such that the valve body is compressed to ensure closing of the slit. Therefore, to make the valve body of '034 of oval shape instead would be obvious in view of the interchangability as taught by '463. In so doing the prior art would necessarily and inevitably teach the peripheral edge also being non-circular when the valve body is unstressed and the width dimension being less than the second height dimension when the valve body is unstressed.

Claim 20: See the portions cited supra, i.e. the recess as discussed with respect to claim 19 supra has a diameter/height dimension which is less than the diameter/height dimension of the valve body.

Claim 22: See the cited portions of '033.

Claim 25: See col. 6, lines 12-19, elements 34A, 34 and 44 and col. 4, lines 10-20, i.e. the external raised ring is the portion of 10A radially outward of the channel which receives ledge 34A but is not denoted in Figure 7, i.e. see element denoted 44 in Figure 3, which ring surrounds the opening. It is noted the claim does not require the ring be raised in any particular direction and/or only be on the second planar face and the portion of 10A is raised/extends diametrically with regard to the remainder of the valve body which includes the second planar face.

Response to Arguments

8. Applicant's remarks have been carefully considered but are either deemed moot, e.g. in that such issues have not been repeated or are deemed not persuasive for the reasons set forth supra with respect to the prior art rejections now applied supra. It is noted with regard to Applicant's remarks of 6-07 on page 15, line 27-28, such remarks are deemed merely speculative absent collaborating evidence. Applicant's remarks with regard to Behnke and Thomas have been considered but such are deemed narrower than the teachings of the references, see the cited portions of '463, and the prior art rejection which is correct except for the typo "121" which has been removed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claim 1, 20, 25 and 27 and paragraph 36.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karin M. Reichle/
Primary Examiner, Art Unit 3761

KMR
February 15, 2008